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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Cardiovascular and Renal Drugs Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on July 18, 2002, from 8 a.m. to 5 p.m. and on July 19, 2002, from 8 a.m. to 3 p.m.

*Location*: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD, 301–652–2000.

*Contact Person*: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, petersonj@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On July 18, 2002, beginning at 8 a.m., the committee will discuss supplemental new drug application (SNDA) 20–838/S–015, ATACAND (candesartan cilexetil) Tablets, AstraZeneca LP, for a proposed claim of

comparative efficacy of candesartan cilexetil and losartan in hypertension. Beginning at 1 p.m., the committee will discuss new drug application (NDA) 21–387, PRAVIGARD PAC (pravastatin sodium/aspirin co-packaged product), Bristol-Myers Squibb Co., proposed for long-term management to reduce the risk of cardiovascular events (death, nonfatal myocardial infarction, myocardial revascularization procedures, and ischemic stroke) in patients with clinically evident coronary heart disease. On July 19, 2002, the committee will discuss NDA 21–188, VANLEV (omapatrilat) Bristol-Myers Squibb Co., proposed for the treatment of hypertension. The background material for this meeting will be posted 1 working day before the meeting on the FDA Web site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.

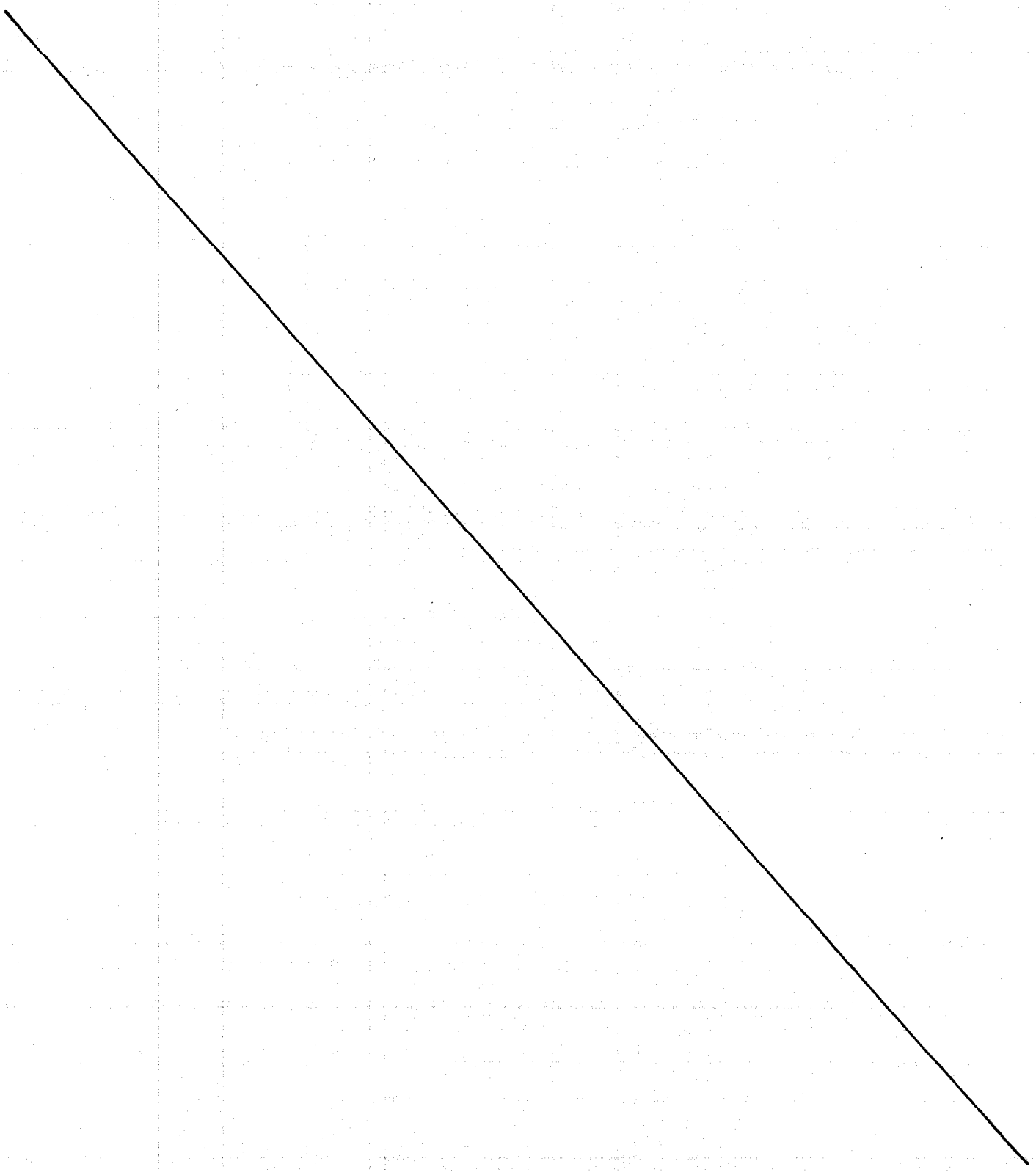
*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 11, 2002. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 10:45 a.m. and 3:15 p.m. and 3:45 p.m. on July 18, 2002, and between approximately 10:15 a.m. and 10:45 a.m. on July 19, 2002.

Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 11, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical

disabilities or special needs. If you require special accommodations due to a disability, please contact Jayne E. Peterson at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 21, 2002.

June 21, 2002.

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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